



04-23-07

IFW

Docket No. TPI5020USPCT1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Julius Remenar et al.

Serial No.: 10/533,420

Group No.: 1743

Filed: 04/29/2005

Examiner: Gakh, Yelena

For: PREFORMULATION ANALYSIS AND OPTIMIZATION

Attorney Docket Number: TPI5020USPCT1

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. § 1.56 and in accordance with 37 C.F.R. §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. § 1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

CERTIFICATE OF MAILING BY EXPRESS MAIL

I hereby certify that under 37 CFR § 1.10 that this correspondence is being deposited on April 20, 2007 with the United States Postal Service as Express Mail Post Office to Addressee with sufficient postage in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


Kristin Miele

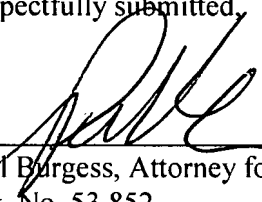
☒ In accordance with §1.97(b), since this Supplemental Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☒ A copy of a PCT International Search Report from the counterpart application is enclosed. Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2).

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/TPI5020USPCT1/PB.

Respectfully submitted,

Dated: 4/20/07
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Paul Burgess, Attorney for Applicants
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Customer No. 27777

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Sheet	3	of	8
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Application Number	10/533,420
Filing Date	04/29/2005
First Named Inventor	Hongming Chen
Art Unit	1743
Examiner Name	Gakh, Yelena
Attorney Docket Number	TP15020USPCT1

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
		WO 01/51919	03-16-2007	Levinson et al.		
		WO 98/52047	11-19-1998	AURORA BIOSCIENCES		
		WO 00/59627	10-12-2000	MILLENNIUM PHARMA		
		EP 0921396	06-09-1999	PFIZER		
		EP 0807811	11-19-1997	PFIZER		
		EP 0882500	12-09-1998	SUMITOMO		

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		EP 0553539	08-04-1993	SCHERING		
		EP 1174183	01-23-2002	SYMYX TECHNOLOGIES		
		EP 1174185	01-23-2002	SYMYX TECHNOLOGIES		
		EP 1186892	03-13-2002	SYMYX TECHNOLOGIES		

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Sheet	5	of	8	Attorney Docket Number	TPI5020USPCT1

NON PATENT LITERATURE DOCUMENTS			
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		BOWTELL, D., "Options available-from start to finish-for obtaining expression data by microarray", Nat Genet, 21 (1 Supp), pgs. 25-32 (1999)	
		BERGLUND et al., "Screening chemical and physical stability of drug substances", J. Phatmac. Biomed. Analysis, 1990, V. 8, No8-12, pp. 639-643	
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		BYRN et al., Pharmaceutical solids: a strategic approach to regulatory considerations", Pharmaceutical Research, 1995, v. 12, No. 7, pp. 945-54	
		CHANDLER et al., "High-throughput Screening Techniques for Pre-formulation: Salt Selection and Polymorph Studies", Acta Cryst., 2002, A58, (Supplement) C9	
		CHAYEN et al., "Microbatch crystallization under oil-a new technique allowing many small-volume crystallization trials", J. of Crystal Growth, 122: pgs. 176-80 (1992)	
		COX et al., "An investigation of protein crystallization parameters using successive automated grid searches (SAGS)", J. of Crystal Growth, 90: pgs. 318-324 (1988)	
		CRAW et al., "Case based design for Tablet Formulation", proc. 4th Eur. Workshop on Case based Reasoning, pgs. 358-369 (1998)	
		CREESE, "Receptor Binding as a Primary Drug Screen", Neurotransmitter Receptor Binding, 2nd Ed., Ch. 9, pgs. 189-233 (1985)	
		ECKSTEIN et al., Unattended, Robotic Drug-Release Testing of Enterically Coated Aspirin", Anal. Chem., 58: pgs. 2316-2320 (1986)	

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Sheet	6	of	8	Attorney Docket Number		TPI5020USPCT1

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		Food and Drug Administration, "International Conference on Harmonisation: Draft Guideline on Impurities..." Federal Register 62: pgs. 24302-09 (1997)	
		GARDNER, "Application of High-Throughput Technologies to Drug Substance and Drug Product Development", FOCAPO, 12 January 2002	
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		GORDON et al., "Combinatorial Organic Synthesis, Library Screening Strategies, and Future Directions", J. Med. Chem., 37(10), pgs. 1384-1401 (1994)	
		HILFIKER et al., Polymorphism - integrated approach from high-throughput screening to crystallization optimization", Journal of Thermal Analysis and Calorimetry, 2003, v. 73,	
		IYER et al., "Studies on Instantaneous release of Drug Compounds for Microfluidic High-throughput Screening Applications", Polymer Preprints: ACS, Division of Polymer Chemistr	
		KORNBLUM, ' Stability Studies of Small Solid Dosage Forms", Drug & Cosmetic Industry, 1970, v. 106, No. 4, pp. 141-146	
		LENCZEWSKI et al., "Automated Screening Method for Determining Optimum Preservative Systems...", Journal of AOAC International, 81: pgs 534-9 (1998)	
		LENNERNAS, "Human Intestinal Permeability", Journal of Pharm. Sci., 87: pgs. 403-410 (1998)	

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Sheet	7	of	8	Attorney Docket Number	TPI5020USPCT1

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		LIPINSKI et al., "Aqueous Solubility in Discovery, Chemistry, and Assay Changes", Methods and Principles in Medicinal Chemistry, 2003, 18 (Drug Bioavailability), pp. 215-231	
		LIPINSKI et al., "Experimental and computational approaches to estimate solubility and permeability in drug discovery...", Advanced Drug Delivery, 2001, v. 46, pp. 3-26	
		LITTLECHILD et al., "Protein crystallization: magical or logical: can we establish some general rules?", J. of Physics, pgs. 111-118 (1991)	
		MARTIN et al., "Automation of Microtiter Plate-Chromogenic Substrate LAL Endotoxin Assay Method...", J. of Parenteral Science and Technology, 4: pgs. 61-6 (1986)	
		MCFARLAND et al., "Combinatorial approaches to materials discovery", Trends Biotechnol., 17(3): pgs. 107-115 (1999)	
		MEHTA, "Issues and approaches for improving the solubility and bioavailability of poorly water soluble compounds", Bulletin Technique Gattefosse, 1998, v. 91, pp. 65-72	
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		MERRITT, A.T., "Uptake of new technology in lead optimization for drug discovery", 1998 DDT, 3(11), pgs. 505-510	
		MORELOCK et al., "Estimation and Correlation of Drug Water Solubility with Pharmacological Parameters Required for...", J. Pharm. Sci., 1994, v. 83, No. 7, pp. 498-52	
		PROMEGA, Inc., "Cell Titer 96 AQueous One Solution Cell Proliferation Assay", 1996 Neural Notes, 11(3), 15	

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Sheet 8 of 8

NON PATENT LITERATURE DOCUMENTS

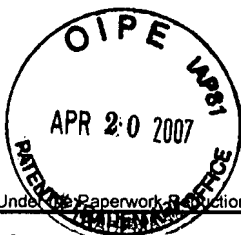
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		SHARMA et al., "Pharmaceutical and Physical Properties of Paclitaxel (Taxol) Complexes with Cyclodextrins", J. Pharm. Sci., 84, 10, pgs. 1223-1230 (1995)	
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		WANG et al., "A New Ultra-high Throughput Method for Characterizing...", Rapid Commun. in Mass Spectrom., 12, pgs. 1123-1129 (1998)	
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		"1998 ARES Meeting Wine Tasting" Online! XP002248070, Retrieved from the Internet: URL: http://www.aresnet.org/ARES/meetings_1998Wine.html retrieved on 7/15/2003	

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		Number-Kind Code ² (if known)			
		US- 3,899,011	08-12-1975	Curtiss	
		US- 5,859,703	01-12-1999	Aldridge et al.	
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		US- 2002/0037647	03-28-200	Hwang et al.	
		US- 2002/0048610	04-25-2002	Cima et al.	

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		WO 94/11489	05-26-1994	BIOLOG, INC.		
		WO 96/06842	03-07-1996	PFIZER LIMITED		
		WO 96/16078	05-30-1996	PFIZER LIMITED		
		WO 99/08112	02-18-1999	SUPRATEK PHARMA INC.		
		WO 98/40159	09-17-1998	TREGA BIOSCIENCES, INC		
		WO 98/47613	10-29-1998	SYMIX TECHNOLOGIES		

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Application Number	10/533,420
Filing Date	04/29/2005
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Art Unit	1743
Examiner Name	Gakh, Yelena
Attorney Docket Number	TP15020USPCT1

U. S. PATENT DOCUMENTS

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
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